

FINAL REPORT

GRANT #: N00014-97-1-1083

PRINCIPAL INVESTIGATOR: John C. Ruckdeschel, M.D.

INSTITUTION: University of South Florida

GRANT TITLE: Advanced Cancer Detection Center

AWARD PERIOD: 1 October 1997 - 31 December 1998

OBJECTIVES: (1) Expand cancer screening and education programs; (2) find cancers in the population early enough to make a difference in morbidity and mortality; (3) research and implement high quality, high technology, and cost effective communication delivery methods via telemedicine and teleconferencing; and (4) implement basic science investigations of early genetic and biochemical transformations related to cancer that can be detected early in the disease process.

APPROACH:

1. *Expand cancer screening & education programs.*
 - a. Identify populations known to be at high risk of developing cancer and address the special needs of regional groups.
 - b. Educate health care professionals to consistently provide early detection and screening strategies to patients seeking health care services.
2. *Find cancers in the population early enough to make a difference in morbidity and mortality.*
 - a. Research the efficacy of prevention strategies utilizing drugs or nutritional and dietary changes.
 - b. Begin testing strategies in clinical trials with targeted groups.
3. *Research and implement high quality, high technology, and cost effective delivery methods via telemedicine and teleconferencing.*
 - a. Implement computer strategies to establish and support a network of professionals who provide cancer screening, early detection and prevention services.
 - b. Provide an infrastructure to deliver educational content and programs to targeted audiences.
4. *Implement basic science investigations of early genetic and biochemical transformations related to cancer that can be detected early in the disease process.*
 - a. Develop and test the ability of genetic markers and molecular changes in pre-neoplastic patients to predict later disease progression.
 - b. Offer genetic testing and counseling to high-risk populations.

ACCOMPLISHMENTS: Eight studies were established to provide clinical services and important new research findings in the areas of breast, cervix, prostate and lung cancer. Important new relationships were established between the Advanced Cancer Detection Center at the H. Lee Moffitt Cancer Center & Research Institute and MacDill Air Force Base, and the Bay Pines and James A. Haley Veterans Administration Medical Centers. Planning progressed in the creation of the necessary infrastructure to support the developing educational mission. New screening services were developed and the capability to meet a growing active duty, retired, and dependent population was created.

Research protocols were designed to provide essential clinical services to meet the needs of the target population as well as answer important research questions. These studies focus on the development and testing

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of new markers for pre-neoplasia and lung cancer among high-risk populations. Several new studies include important genetics screening and testing services which heretofore have not been available in the region. Medical Informatics technologies have been further developed to keep pace with the rapidly changing digital environment. The necessary equipment has been purchased to utilize these technological advances to be able to produce educational programming to the desktop via the Moffitt Cancer Network. Additional mobile equipment has been purchased to expand the availability of these services to the target populations and areas.

To develop programming for the Moffitt Cancer Network, and to create other educational products for the audiences served by this grant, the Multimedia Educational Resource Center has been created. This team of multimedia specialists, artists, audio/visual specialists, and photographers work collaboratively with other Moffitt professionals in education and medical informatics to exploit the multimedia, internet-based technology that can extend our resources and create an interactive educational community.

Additional equipment has been purchased to better serve audiences not near the Moffitt campus. Mobile units for the Lifetime Cancer Screening Center, and the professional health educators and nurse practitioners that staff them, are able to provide cancer screening services, including mammography and sputum induction, at sites where those best served by the grant are located. Working relationships with both area VA hospitals and MacDill Air Force Base have been established to allow our mobile units to serve clientele at those locations.

CONCLUSIONS: Continue to accrue large numbers of subjects for the studies developed. A cohort in excess of 3,000 individuals at high risk for lung cancer needs to be developed to screen for markers of pre-neoplasia and also to enroll subjects in pilot studies designed to prevent this disease. Continue to develop and test new molecular markers and explore their applicability to breast and cervical cancer. Linkage studies should help identify chromosomal abnormalities associated with prostate cancer in multiply affected families. Investments need to be made to expand the genetics programs and to continue the production and distribution of educational programming over the Internet, and the specially constructed Extranet. Additional staff need to be recruited for patient enrollment and data collection.

We plan to expand our genetic services to include an affiliation with the genetics laboratory at Keesler Air Force Base and provide the data system support for genetics DOD-wide. Our partnership with Keesler and active involvement with MacDill will lead to the establishment of a regional genetics center for Region 3 at MacDill. To acquaint healthcare providers in the region with the need and value of genetic counseling and screening services, we sponsored a conference in clinical genetics and offered free enrollment to all military and VA healthcare providers. A program in cancer and literacy was offered in April, 1998. For those who were unable to attend, the genetics conference proceedings are being prepared for widespread distribution. Online distribution of educational programming will be more readily accessed and content will be expanded. Satellite facilities for the Advanced Cancer Detection Center are to be established at the James A. Haley VA and negotiations are underway to establish similar facilities at our other sites.

As the project progresses, we expect increasing numbers of patients to be enrolled on research and clinical studies to avail themselves of advanced technology that has been developed. Continued emphasis will be

in the translation of basic science laboratory methods into the clinical cancer control setting for new methods for screening early detection. The number of studies available for the prevention of cancer will expand in parallel as we seek to create more options for those identified at high risk for developing cancer. Expanded opportunities to serve our target population will come from closer ties with Champus Tricare Provider as we explore and demonstrate the cost-effectiveness of early screening and detection strategies.

SIGNIFICANCE: A multidisciplinary team of researchers, clinicians and data management staff generally develops clinical protocols. Moffitt's Scientific Research Committee first reviews draft protocols; pending approval there, protocols move on to the University of South Florida Institutional Review Board (USF IRB) for approval. Moffitt Research Administration Projects Office staff are involved in all steps of the protocol development, approval and implementation process. Moffitt Data Management staff coordinate protocol implementation working collaboratively with investigators, nurses, hospital departments such as pharmacy and specimen processing.

The methodologies of the educational efforts of the project are implemented, to a large degree, via The Moffitt Channel. This interactive network of internet-based channels delivers a variety of programming and services to selected users. Programming includes: The Video Classroom and the Moffitt World Wide Web Home Page.

The Video Classroom provides programs to health care providers that are convenient to view and meet their continuing education needs. It allows users to virtually attend educational programs by viewing videos on demand.

The Moffitt Home Page (<http://www.moffitt.usf.edu>) is the front page of the Center. It summarizes institutional goals and news, provides information on patient referral, displays directions to Moffitt and provides full-text access to the *Cancer Control Journal*, with 4 CME credits in each issue.

Users connect to The Moffitt Network via a standard web browser on their personal computers. Users then download audio-video plug-ins to view The Moffitt Network programs.

Other educational efforts have involved conferences, at which oncology professionals drawn from an international pool of experts have gathered to discuss two important topics:

- Cancer, Culture & Literary, on reaching underserved, culturally diverse audiences with effective cancer education materials; and
- Cancer Genetics, which explored the interactions between cancer development and genetic understanding. Our military partners were invited to attend at no cost; those who were unable to attend will receive, also at no cost, printed proceedings of these conferences.

PATENT INFORMATION: None

AWARD INFORMATION: None

PUBLICATIONS AND ABSTRACTS:

Shaw, GL, Walsh FW, Rolfe MW, Cantor AB, Vann V, Khoor A: Value of Fluorescent Bronchoscopy in Identifying Bronchial Metaplasia and Dysplasia in Smokers. 1999 Annual Meeting of the American Society of Clinical Oncology.

LUC: Lung Cancer**150599****Shaw, Gail**

1999 Annual Meeting of the American Society of Clinical Oncology

Presenting Author: Gail L. Shaw**Institution:** H. Lee Moffitt Cancer Center & Research Institute at the University of South Florida, Tampa, Florida, 33612.**Address:** 12902 Magnolia Drive, Tampa, Florida, 33612**Phone:** (813) 632-1329 **Fax:** (813) 632-1334 **E-Mail:** shaw@moffitt.usf.edu**Abstract Categories:** LUC, Lung Cancer**Format Preference:** Slide or Poster presentation **Awards:****Audio/Visual:** Yes**Sponsor:** Gail L. Shaw, M.D. **Sponsor Fax:** (813) 632-1334**Value of Fluorescent Bronchoscopy in Identifying Bronchial Metaplasia and Dysplasia in Smokers.**G L Shaw¹, F W Walsh¹, M W Rolfe¹, A B Cantor¹, V Vann¹ and A Khoor¹. ¹H. Lee Moffitt Cancer Center & Research Institute at the University of South Florida, Tampa, Florida.

Although cigarette smoking is the principle etiologic agent in over 80% of lung cancer, identifying which smokers are at greatest risk of developing lung cancer would facilitate targeting this very high-risk population for early detection and prevention measures. Squamous metaplasia (SM) and dysplasia (D) of the bronchial epithelium may be useful markers of this potential lung cancer risk. We evaluated the predictive value of the laser-induced fluorescence emission (LIFE) system in detecting SM and D. Bronchoscopy was performed on 14 current and 19 former smokers with a mean of 70 and 45 pack years of smoking respectively. All participants had SM or D on sputum cytology. 158 bronchial biopsies were obtained from 5 predetermined sites regardless of appearance and all abnormal areas by LIFE bronchoscopy. LIFE classes II and III reportedly identify inflammation/mild dysplasia and moderate to severe dysplasia respectively. Biopsies revealed 113 sites were normal, 43 were SM or D, and 2 were insufficient. 111 sites were normal and 47 abnormal by LIFE bronchoscopy (class II in 45, class III in 2). 12 of the 45 class II sites demonstrated SM or D for a positive predictive value of 27%. Both class III sites showed no pathologic abnormality. Of the 111 normal appearing sites, 31 showed SM or D (28%). White light bronchoscopy findings revealed 142 normal appearing sites and 16 abnormal sites. 29% of the normal appearing and 13% of the abnormal appearing sites demonstrated SM or D. Overall, LIFE and white light findings correlated positively ($p=0.0055$). However, neither LIFE nor white light observations correlated with the histopathology (Spearman correlation coefficients -0.0003 and -0.1008 respectively). Current smoking was predictive of dysplasia ($p=0.0046$). In this population of high-risk, current and former smokers, we conclude LIFE bronchoscopy does not improve the yield of detecting SM or D.

I certify that the essential findings of this abstract have not been submitted for publication prior to Monday, December 7, 1998.

Gail L. Shaw
First Author Signature (Gail L. Shaw)

12/4/98
Date

Gail L. Shaw
Sponsoring Member Signature (Gail L. Shaw, M.D.)
Fax ((813) 632-1334)

12/4/98
Date

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